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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,411	01/16/2004	Elizabeth A. Gomez	03US7005	7477

23397 7590 10/04/2005

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EXAMINER

FOSTER, CHRISTINE E

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,411

Applicant(s)

GOMEZ ET AL.

Examiner

Christine Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 13-22 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/27/04, 4/30/04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a method for detecting the presence of an autoantibody, classified in class 436, subclass 526.
- II. Claims 6-12, drawn to a method for detecting anti-intrinsic factor autoantibody, classified in class 436, subclass 542.
- III. Claims 13-22, drawn to a test kit for performing an assay, classified in class 422, subclass 61.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are independent and patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent and patentably distinct methods that differ with respect to one or more of ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct.

Group I is drawn to a method for detecting the presence of an autoantibody, which includes the step of separating a solid phase from a liquid phase, which is not a limitation of Group II. Group II is drawn to a method for detecting anti-intrinsic factor autoantibody, which includes the step of adding an interference blocking reagent, which is not a limitation of Group I.

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Furthermore, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these inventions together.

Inventions (I, II) and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the test kit of Group III may be used in either of the methods of Groups I or II.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, and the searches required for one group are not required for the others, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for

patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Mitchell Alter on August 1, 2005 a provisional election was made with traverse to prosecute the invention of Group III, claims 13-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

Applicant's Information Disclosure Statements filed 4/27/04 and 4/30/04 has been received and entered into the application. The references therein have been considered by the examiner as indicated on the attached form PTO-1449.

Specification

The abstract of the disclosure is objected to because of grammatical errors. The second sentence is a run-on sentence, such that is unclear what the words "is added" refer to in line 5. Also, Applicant may wish to amend line 2 to for proper subject-verb agreement of "autoantibodies" with "interferes." Correction is required. See MPEP § 608.01(b).

The use of trademarks (UniCel, Synchron LX, Lumi-Phos) has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a test kit for detection of autoantibodies specific for intrinsic factor that interfere with vitamin B12 binding to intrinsic factor ("blocking" or "type I" antibodies), does not reasonably provide enablement for kits for detection of all autoantibodies specific for all receptors with autoantibody binding sites. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to a test kit for detection of autoantibodies in a sample. The test kit includes a receptor that is recognized by the autoantibody being detected; the receptor is labeled for use in the kit. The kit also comprises a binding pair member such as an antibody that binds to the labeled receptor at the same site on the receptor that is bound by the autoantibody. The binding pair member is bound to a solid phase for use in the kit. An interference blocking agent is also included, which specifically binds to a substance in the test sample that is capable of binding to the same site on the receptor that can be bound by either the autoantibody or the binding pair member. The autoantibodies in the sample compete with the binding pair member for binding to the labeled intrinsic factor, allowing for detection of sample autoantibody.

The specification discloses that intrinsic factor is recognized by autoantibodies, including "blocking" or Type I autoantibodies that block the vitamin B12 binding site on intrinsic factor (IF) (see the specification p. 1-2, paragraph 4). As the binding pair member, the specification discloses mouse monoclonal anti-IF, which binds to the B12 binding site on IF (p. 9, paragraph 33). Working Example I (p. 9-11) describes assays employing mouse anti-IF.

The specification also suggests that the binding pair member may be “selected so that if Type II antibody binds to the labeled intrinsic factor, labeled IF is hindered from binding to the binding pair member-coated solid phase” (p. 7, paragraph 25). However, there is no further disclosure of this latter type of binding pair member and there are no examples directed to a kit comprising such a member. The prior art teaches that Type II IF antibodies detect an antigen site unrelated to the B12 binding activity (Waters et al., “New enzyme immunoassay for detecting total, type I, and type II intrinsic factor antibodies” (1989) *J. Clin. Pathol.* **42**:307-312); therefore, Type II autoantibodies would not be expected to compete with the mouse monoclonal anti-IF disclosed, as the mouse antibody is specific for the B12 binding site. In addition, the feasibility of detecting Type II autoantibodies in patient samples by competition immunoassay with monoclonal B12-binding site IF antibodies on a solid phase has not yet been characterized (Gomez et al., “Development and Validation of an Automated Chemiluminometric Immunoassay for Human Intrinsic Factor Antibodies in Serum” (2005) *Clin. Chem.* **51**:232-235; in particular p. 233, Figure 1, and p. 234, right column, last full paragraph).

The claims are broadly drawn to include receptors that are “any protein or binding factor present in a living organism having binding sites to which autoantibodies may bind and either block the binding of a molecule or protein that naturally binds to the receptor or that when bound stimulates the release of a hormone” and lists the examples of IF, thyroid stimulating hormone, folate stimulating factor, and insulin receptors (p. 3, paragraph 10). However, there is no disclosure of autoantibodies that recognize receptors other than IF or of sites on such receptors that are recognized by autoantibodies. Further, there is no disclosure of binding pair members capable of binding receptors other than IF at sites that are recognized by autoantibodies. There is

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also no disclosure of interference blocking reagents that recognize substances capable of binding to autoantibodies specific for receptors other than IF.

In conclusion, the prior art fails to establish the feasibility of detecting type II IF autoantibodies using the assay format of the invention, as type II antibodies are not known to compete with B12-binding site antibodies for binding to IF. Therefore, due to the state of the prior art, the lack of direction/guidance presented in the specification regarding detection of autoantibodies binding to receptors sites other than IF autoantibodies that bind to the B12-binding site, as well as the lack of direction/guidance regarding binding pair members that bind to autoantibody binding sites other than to the B-12 binding site of IF, the lack of working examples directed to detection of autoantibodies other than type I IF antibodies, and in particular detection of other receptor autoantibodies, and the breadth of the claims, the specification fails to teach the skilled artisan how to make and use the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-16 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Newman et al. (US Patent No. 6,942,977, filed May 28, 1993) or, alternatively, Newman et al.

(Canadian Patent Application 2,110,109, Information Disclosure Statement filed 4/30/04). The column and line numbers cited below in reference to Newman et al. refer to the US Patent.

Newman et al. teach diagnostic kits for assaying vitamin B12 comprising a receptor (intrinsic factor) that has a specific binding site for an autoantibody that directly blocks binding to vitamin B12 (column 1, lines 54-58) and a binding pair member capable of binding the receptor (antibody that specifically binds to intrinsic factor), wherein either the intrinsic factor or the antibody is labeled and one of them is immobilized on a solid support (column 4, lines 1-21). The antibody to intrinsic factor may be an antibody that is specific for the vitamin B12 binding site of intrinsic factor, and may be bound to a solid support (column 2, lines 8-22; column 2, line 63 to column 3, line 5; column 6, lines 12-17 in particular). Newman et al. further teach an interference blocking reagent, such as dextran-coated charcoal, that will specifically extract free vitamin B12 (which specifically binds to the vitamin B12 binding site of intrinsic factor) but not monoclonal antibodies from the sample (column 5, lines 23-36).

With regard to claims 14 and 21, the solid support may be magnetic particles (column 6, lines 45-52).

With regard to claims 15 and 20, the intrinsic factor may be labeled with alkaline phosphatase (column 8, line 30-47 and column 6, line 53 to column 7, line 3).

With regard to claim 22, the anti-intrinsic factor antibody is a monoclonal antibody (the abstract and column 2, lines 8-11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al. (US Patent No. 6,942,977) or, alternatively, Newman et al. (Canadian Patent Application 2,110,109) view of Pourfarzaneh (US Patent No. 5,564,104). Newman et al. is as discussed above, which fails to teach a method wherein the interference blocking reagent is an antibody to vitamin B12.

Pourfarzaneh teaches methods of removing labeled molecules from solution (column 2, lines 5-34 and Table A in particular). In particular, Pourfarzaneh teach that the molecules may be bound by binders such as charcoal adsorbents or monoclonal antibodies capable of binding the molecules (column 2, lines 20-34; column 8, lines 8-45 in particular). Examples of biological molecules that may be removed from solution include radiolabeled vitamin B12 (column 2, lines 14-16 in particular).

It would have been obvious to one of ordinary skill in the art to employ the monoclonal antibodies capable of binding to vitamin B12 taught by Pourfarzaneh in place of the dextran coated charcoal of Newman et al. in order to remove free vitamin B12 from samples containing antibodies to intrinsic factor, and because Newman et al. teach that removing free vitamin B12 is important in the identification of antibodies that will not be able to bind intrinsic factor or that will be released from binding in the presence of vitamin B12, which would be particularly

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difficult to detect if there were even trace amounts of vitamin B12 present (see Newman et al., the abstract and column 5, lines 23-36 in particular). One would have reasonable expectation of success because Pourfarzaneh teaches that both charcoal and monoclonal antibodies capable of binding to vitamin B12 may be used to remove molecules such as vitamin B12 from solution.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Newman et al. (US Patent No. 6,942,977) or, alternatively, Newman et al. (Canadian Patent Application 2,110,109) in view of Pourfarzaneh as applied to claims 17-18 above, and further in view of Herbert (US Patent No. 4,680,273). Newman et al. and Pourfarzaneh are as discussed above, which fail to teach a test kit comprising R-protein as the interference blocking reagent.

Herbert teaches that R-protein is a binder for total corrinoids, including vitamin B12, which can be used to bind to vitamin B12 in solution (see column 4, in particular lines 58-62, and column 5, lines 1-42). R-protein may be used alone or in conjunction with the use of coated charcoal (column 5, lines 35-42).

Therefore, it would have been obvious to employ R-protein as the interference blocking reagent as taught by Herbert in the method of Newman et al. and Pourfarzaneh in order to remove free vitamin B12 from samples containing antibodies to intrinsic factor. One would have reasonable expectation of success in substituting R-protein for the monoclonal antibodies capable of binding vitamin B12 because Herbert teaches that R-protein are capable of binding vitamin B12, which is also the purpose of the charcoal and monoclonal antibodies taught by Newman et al. and Pourfarzaneh. In addition, Herbert teaches that R-protein may be used as a vitamin B12 binder in conjunction with coated charcoal methods, such as that of Newman et al.

Claims 13-16 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. ("A Rapid Fully Automated Assay For the Detection of Intrinsic Factor Blocking Antibodies on Beckman Coulter's Access Immunoassay System" (June, 2001) *Clinical Chemistry* Vol. 47, No. S6, pp. A12 (print); Meeting Info: 53rd Annual Meeting of the AACC/CSCC. Chicago, IL, USA, July 29-August 02, 2001, American Association for Clinical Chemistry) in view of Newman et al. (US Patent 6,942,977).

Smith et al. teach an assay for detection of intrinsic factor blocking autoantibodies which comprises intrinsic factor-alkaline phosphatase conjugate and a monoclonal antibody (mouse anti-IF) capable of binding to intrinsic factor at or near the binding site of an autoantibody, in this case intrinsic factor blocking antibody. The assay is performed by combining a sample with the intrinsic factor conjugate and mouse anti-IF paramagnetic particles. It would have been obvious to one of ordinary skill in the art to package the ingredients in containers as a test kit in order to employ the assay for diagnostic use (see Smith et al., Conclusion).

Smith et al. fail to teach an interference blocking reagent that will specifically bind to a substance in the sample that is capable of binding to the autoantibody binding site of the labeled receptor. Smith et al. also fail to teach an interference blocking reagent that will specifically bind to vitamin B12, that is an antibody to vitamin B12, or that is R-protein.

Newman et al., as discussed above, teaches interference blocking reagents such as dextran coated charcoal that specifically extract free vitamin B12 but not monoclonal antibodies from the sample in order to remove free vitamin B12 from the sample, which is important in the identification of antibodies that will not be able to bind intrinsic factor or that will be released from binding in the presence of vitamin B12, which would be particularly difficult to detect if

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there were even trace amounts of vitamin B12 present (see Newman et al., the abstract and column 5, lines 23-36 in particular).

Therefore, it would have been obvious to one of ordinary skill in the art to employ an interference blocking reagent as taught by Newman et al. in the method of Smith et al. in order to remove free vitamin B12 from the sample. One would have reasonable expectation of success because Newman et al. teaches the importance of removing free vitamin B12 in a method for detection of competitive antibodies to intrinsic factor, such as that of Smith et al.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Newman et al. as applied to claims 13-16 and 20-22 above, and further in view of Pourfarzaneh. Smith et al. and Newman et al. are as discussed above, which fail to teach a method wherein the interference blocking reagent is an antibody to vitamin B12.

Pourfarzaneh teaches methods of removing labeled molecules from solution (column 2, lines 5-34 and Table A in particular), in which the molecules may be bound by binders such as charcoal adsorbents or monoclonal antibodies capable of binding the molecules (column 2, lines 20-34; column 8, lines 8-45 in particular). Examples of biological molecules that may be removed from solution include radiolabeled vitamin B12 (column 2, lines 14-16 in particular).

It would have been obvious to one of ordinary skill in the art to employ the monoclonal antibodies capable of binding to vitamin B12 taught by Pourfarzaneh in place of the dextran coated charcoal of Newman et al. in order to remove free vitamin B12 from samples containing antibodies to intrinsic factor, and further because Newman et al. teach that removing free vitamin B12 is important in the identification of antibodies that will not be able to bind intrinsic factor or that will be released from binding in the presence of vitamin B12, which would be particularly

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difficult to detect if there were even trace amounts of vitamin B12 present (see Newman et al., the abstract and column 5, lines 23-36 in particular). One would have reasonable expectation of success because Pourfarzaneh teaches that both charcoal and monoclonal antibodies capable of binding to vitamin B12 may be used to remove molecules such as vitamin B12 from solution.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Newman et al. and Pourfarzaneh as applied to claims 17-18 above, and further in view of Herbert. Smith et al., Newman et al. and Pourfarazeneh are as discussed above, which fail to teach a test kit comprising R-protein as the interference blocking reagent.

Herbert teaches that R-protein is a binder for total corrinoids, including vitamin B12, which can be used to bind to vitamin B12 in solution (see column 4, in particular lines 58-62, and column 5, lines 1-42). R-protein may be used alone or in conjunction with the use of coated charcoal (column 5, lines 35-42).

Therefore, it would have been obvious to employ R-protein as the interference blocking reagent as taught by Herbert in the method of Newman et al. and Pourfarzaneh in order to remove free vitamin B12 from samples containing antibodies to intrinsic factor. One would have reasonable expectation of success in substituting R-protein for the monoclonal antibodies capable of binding vitamin B12 because Herbert teaches that R-protein are capable of binding vitamin B12, which is also the purpose of the charcoal and monoclonal antibodies taught by Newman et al. and Pourfarzaneh. In addition, Herbert teaches that R-protein may be used as a vitamin B12 binder in conjunction with coated charcoal methods, such as that of Newman et al.

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Conclusion

No claims are allowed. The following are also cited by the examiner as prior art of relevance:

Conn ("Detection of Type I and Type II antibodies to intrinsic factor" (1986) *Medical Laboratory Sciences* 43:148-151) teaches reagents including radiolabeled intrinsic factor for detection of intrinsic factor autoantibodies. However, Conn fails to teach the use of a binding pair member bound to a solid phase or an interference blocking reagent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christine Foster
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09/29/05